UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

GREGORY MAYES, an individual, Plaintiff, vs. ELI LILLY AND COMPANY, a corporation; and DOES 1 through 50, inclusive, **Defendants.**	Case No.: 14-CV-1759 JUDGE PEARSON MAGISTRATE JUDGE BURKE **FIRST AMENDED COMPLAINT**

COMES NOW Plaintiff, Gregory Mayes, by and through undersigned counsel, and for his cause of action files this First Amended Complaint for damages against the above-named Defendant alleging the following:

INTRODUCTION

1. This is a civil action for products liability alleging personal injuries and damages, including serious and life-threatening withdrawal symptoms, suffered by Plaintiff Gregory Mayes as a direct and proximate result of his ingestion and cessation of the prescription drug, Cymbalta (duloxetine), which is manufactured, marketed, and sold by Defendant Eli Lilly and Company (hereinafter, "Defendant" or "Lilly").

PARTIES

2. Plaintiff Gregory Mayes (hereinafter, "Plaintiff") is, and at all times relevant to this Complaint was, a citizen of the State of Ohio and resident of Mahoning County.

3. Defendant Eli Lilly and Company is, and at all times relevant to this Complaint was, an Indiana corporation with its headquarters in Indianapolis, Indiana. Lilly is a pharmaceutical company involved in the research, development, testing, manufacture, production, promotion, distribution, marketing and sale of numerous pharmaceutical products, including Cymbalta, a prescription antidepressant drug.

4. Plaintiff does not know the true names and identities of those defendants designated as DOES 1 through 50, inclusive, but alleges that each of said fictitiously named defendants was

negligently and unlawfully responsible for the events herein described, and for the injuries and damages sustained by Plaintiff, Gregory Mayes, and Plaintiff will ask leave of court to amend this complaint when the identity of each such fictitiously named defendant has been ascertained

5. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority. During the relevant times, Defendants possessed a unity of interest between themselves. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's damages.

JURISDICTION AND VENUE

6. This Court has personal jurisdiction over Lilly insofar as Lilly is authorized and licensed to conduct business in Ohio, maintains and carries on systematic and continuous contacts in this judicial district, regularly transacts business within this judicial district, and regularly avails itself of the benefits of this judicial district.

7. Furthermore, Lilly has caused tortious injury by acts and omissions in this judicial district and caused tortious injury in this district by acts and omissions outside this district while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in this judicial district.

8. This Court has subject matter jurisdiction in the form of diversity jurisdiction, pursuant to 28 U.S.C.A. § 1332, in that there is a complete diversity of citizenship between Plaintiff and Defendant and the amount in controversy exceeds $75,000.00.

9. Venue is proper pursuant to 28 U.S.C. § 1391.

FACTUAL ALLEGATIONS

10. Lilly is one of the largest pharmaceutical companies in the world with annual revenues exceeding $20 billion. A substantial portion of Lilly's sales and profits have been derived from its drug Cymbalta, whose 2009 annual sales exceeded $3 billion, making it the second most profitable drug in Lilly's current product line.

11. Lilly has enjoyed considerable financial success from manufacturing and selling prescription drugs for the treatment of clinical depression, including the popular antidepressant Prozac (generically known as fluoxetine). Lilly launched Prozac in 1988 touting it as the first

"Selective Serotonin Reuptake Inhibitor" ("SSRI"). SSRIs are a class of antidepressant drugs that were promoted as increasing the brain chemical serotonin in the synaptic clefts between the neurons in the brain. It has been theorized that reduced levels of serotonin cause depression; however, recent studies have undermined this theory. Prozac became extremely popular in the 1990s and was the top-selling antidepressant of its kind. Prozac's patent expired in August 2001.

12. In 2001, Lilly needed to fill the void left behind by Prozac's patent expiration, and so it sought approval by the Food and Drug Administration's ("FDA") for its next antidepressant, Cymbalta. Unlike Prozac, Cymbalta is a "Serotonin-Norepinephrine Reuptake Inhibitor" ("SNRI"), which Lilly promoted as increasing the brain chemicals serotonin and norepinephrine in the synaptic clefts between the neurons in the brain. Lilly and other SNRI manufacturers admit that the precise mechanism of action is not clear, however, they have promoted the drugs by stating that higher levels of these neurotransmitters somehow improve and elevate mood.

13. In 2003, the FDA initially rejected Lilly's application to approve Cymbalta due to certain violations of good manufacturing practices and the risk of liver toxicity apparent in the drug's safety profile.

14. Eventually, in 2004, manufacturing issues were resolved and the FDA approved Cymbalta with a liver toxicity warning included in the prescribing information. The drug was approved for Major Depressive Disorder ("MDD"). In 2007, the FDA approved Cymbalta for treatment of Generalized Anxiety Disorder ("GAD") and in 2008 for treatment of fibromyalgia.

15. Since the FDA's initial approval of Cymbalta in 2004, Lilly has aggressively marketed the drug to the public and the medical community, spending hundreds of millions of dollars each year on advertising and promotion. Lilly has promoted Cymbalta directly to consumers, including Plaintiff, through all major media channels, including internet, print and television. In addition, Lilly has promoted Cymbalta to the medical community by utilizing its well-organized army of sales representatives to personally visit physicians and health care professionals to distribute free drug samples and promotional literature. Lilly further promoted Cymbalta through advertisements in medical journals and presenting talks and exhibits at medical conferences.

16. Lilly's promotional campaigns have continuously overstated the efficacy of Cymbalta

and understated, downplayed, and/or failed altogether to state the true withdrawal side effects associated with Cymbalta.

17. Presently and at all times material herein, the Cymbalta label provided the following precaution regarding discontinuation: "Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at a rate greater than or equal to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo...."

18. In addition to using the euphemistic term "discontinuation" to describe withdrawal side effects, Lilly also made it appear that such discontinuation symptoms were rare and only affected approximately 1% of Cymbalta users.

19. To the contrary, according to a January 2005 article published in the Journal of Affective Disorders, Lilly's Cymbalta clinical trials showed that a significant percentage (44.3%) of Cymbalta patients suffered from "discontinuation" side effects. David G. Peahia *et al.*, Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder, 89 JOURNAL OF AFFECTIVE DISORDERS 207 (2005). In this published, peer-reviewed paper, the withdrawal side-effect rates for Cymbalta were nearly double that experienced by placebo users, and these findings were statistically significant. Accordingly, the rate of withdrawal or "discontinuation" for Cymbalta (as established by Lilly's clinical trials) was 44.3%, yet in its packaging label, Lilly misleadingly presented this rate as approximately 1%.

20. Moreover, Lilly's clinical trials showed that, overall, 9.6% of Cymbalta users suffered *severe* withdrawal side effects, yet nowhere in the label does Lilly inform practitioners and patients of that risk.

21. Cymbalta's withdrawal side effects include, among other things, headaches, dizziness, nausea, fatigue, diarrhea, paresthesia, vomiting, irritability, nightmares, insomnia, anxiety, hyperhidrosis, sensory disturbances, electric shock sensations, seizures and vertigo. When patients try to stop taking Cymbalta, the side effects can be severe enough to force them to start taking

Cymbalta again, not to treat their underlying condition, but simply to stop the withdrawal symptoms. Patients thus become prisoners to Cymbalta, and Lilly financially benefits by having a legion of physically dependent, long-term users of Cymbalta.

22. Notwithstanding Lilly's knowledge of the high rate of withdrawal symptoms in patients stopping Cymbalta, Lilly failed to adequately, properly, and fully warn patients and physicians about the risk.

23. Instead, in its product labeling, marketing and advertising, and in information made available to consumers and physicians, Lilly reported a far lower risk, downplayed any difference in the withdrawal risk for Cymbalta as compared to other similar antidepressants, and affirmatively misled the consuming patient population and mischaracterized the drug's risk profile.

24. In addition to failing to adequately warn about the actual rate and severity of withdrawal side effect risks, Lilly also overplayed the efficacy of Cymbalta. Seeking to capture a greater segment of the antidepressant market, in 2005, Lilly initiated the direct-to-consumer marketing campaign: "Depression hurts. Cymbalta can help." Cymbalta advertisements bearing this slogan appeared ubiquitously on television, in print and on the internet. Lilly's advertising campaign made it appear that Cymbalta not only treated depression but that it also treated physical pain associated with depression. Scientists reviewing the Cymbalta data have concluded that Lilly's claims are misleading. For example, in a 2008 article published in Psychotherapy and Psychosomatics, the author concluded that "the marketing of duloxetine as an antidepressant with analgesic properties for people with depression does not appear to be adequately supported."

25. Lilly has also augmented its misleading advertising campaigns by engaging in selective and biased publication of its clinical trials of Cymbalta. By way of example, Lilly has generally published only favorable studies of its Cymbalta clinical trials and refused to publish any of the negative and unfavorable studies. Such selective publication of clinical trial data gives the impression that the drug is safer and more effective than it actually is. In a recent study published in the New England Journal of Medicine, researchers obtained clinical trials for antidepressants (including Cymbalta) that had been submitted to the FDA and compared them with studies that had been published. The authors found that there was a "bias towards the publication of positive

results" and that, "according to the published literature, it appeared that 94% of the trials conducted were positive. By contrast, the FDA analysis shows that 51% were positive." The authors found that, as a result of such selective publication, the published literature conveyed a misleading impression of Cymbalta's efficacy resulting in an apparent effect-size that was 33% larger than the effect size derived from the full clinical trial data. See Erick H. Turner *et al.*, Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy, 358 NEW ENG. J. MED. 252 (2008).

26. Lilly's misleading direct-to-consumer promotional campaigns, its misleading presentation of Cymbalta's efficacy and its failure to adequately warn regarding Cymbalta's withdrawal and dependency side effects have paid off financially for Lilly. Cymbalta has become a "blockbuster" drug with over $3 billion dollars in annual sales. In the past few years, Cymbalta has been the second most profitable drug in Lilly's product line. Coincidently, the only drug ahead of Cymbalta is Zyprexa, an antipsychotic drug that Lilly promoted illegally. Indeed, in 2009, Lilly agreed to plead guilty and pay $1.415 billion to the federal government for illegally promoting Zyprexa. This resolution included a criminal fine of $515 million, which, at the time, was the largest settlement ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind.

27. Lilly had the knowledge, the means and the duty to provide adequate warnings regarding Cymbalta's common and severe withdrawal and dependency side effects as well as a duty to honestly portray the safety and efficacy of Cymbalta. Lilly could have relayed these warnings through the same means it utilized to advertise its products, which included but are not limited to its labeling, "Dear Doctor letters," advertisements and sales representatives.

28. In October 2012, the Institute for Safe Medication Practices (ISMP), a non-profit healthcare consumer safety watchdog, issued findings from its independent investigation of Cymbalta adverse events found in the FDA Adverse Event Reporting System (FAERS). *See* QuarterWatch, *Monitoring FDA MedWatch Reports*, Why Reports of Serious Adverse Drug Events Continue to Grow, Oct. 3, 2012, ISMP.

29. The report announced that the investigation uncovered "a signal for serious drug

withdrawal symptoms associated with duloxetine (CYMBALTA)," and detailed for the public what Lilly has long known: "[W]ithdrawal symptoms were reported in 44-50% of patients abruptly discontinuing duloxetine at the end of clinical studies for depression, and more than half of this total did not resolve within a week or two." *Id.* at 11

30. The ISMP report continued: "[W]e identified a serious breakdown at both the FDA and the manufacturer, Eli Lilly and Company, in providing adequate warnings and instructions about how to manage this common adverse effect." *Id.*

31. Explaining the lack of adequate warnings, the ISMP stated:

> Instead of clear warnings and useful instructions, the duloxetine patient Medication Guide says only:
>
> > "Never stop an antidepressant medicine without first talking to a healthcare provider. Stopping an antidepressant medicine suddenly can cause other symptoms."
>
> This FDA-approved patient guide is materially deficient. It gives no hint of the persistence or severity of the symptoms known to occur.
>
> ….
>
> We could not identify any FDA-approved or company information for patients about how to discontinue duloxetine. *Id.* at 12-13.

32. In conclusion, the report minced no words in its indictment of Lilly's product information: "A major lapse has occurred in the FDA-approved information for patients about the risks of stopping duloxetine." *Id.* at 15.

33. Falsely reassured by the misleading and deceptive manner in which Lilly reported Cymbalta's withdrawal risk, physicians, including Plaintiff's physician, have prescribed, and continue to prescribe, Cymbalta to patients without adequate, accurate and proper warnings relating to discontinuation of the drug.

34. On or around September 7, 2012, Plaintiff was prescribed Cymbalta by his physician, for the treatment of anxiety.

35. Around October of 2012, Plaintiff began to feel unlike himself while ingesting Cymbalta. As a result, Plaintiff elected to stop taking Cymbalta.

36. Upon discontinuing Cymbalta, Plaintiff experienced severe and dangerous withdrawal symptoms. By way of example, Plaintiff experienced brain zaps, hallucinations, and suicidal thoughts.

37. At all times relevant, Lilly knew or should have known that Cymbalta was in a defective condition and was and is inherently dangerous and unsafe when used in the manner instructed and provided for by Lilly.

38. At all times relevant, Lilly knew or should have known of the significantly increased risk of withdrawal symptoms, including their severity and duration, posed by Cymbalta and yet failed to adequately warn about said risks.

39. At all times relevant, Lilly engaged in a willful, wanton, and reckless conduct, including its defective design of Cymbalta, its failure to warn about Cymbalta's risks, and its pattern of affirmative misrepresentations and omissions relating to the safety and efficacy of Cymbalta. It overstated the drug's efficacy, downplayed withdrawal side effects, and misstated the actual risk and severity of side effects, all of which induced physicians to prescribe Cymbalta and consumers to use it, including Plaintiff and his physicians.

40. Plaintiff's use of the drug and consequent injuries and damages were a direct and proximate result of Lilly's acts and omissions relating to Cymbalta.

41. If Lilly had adequately, accurately and properly warned about the withdrawal risk associated with Cymbalta, including the high risk of experiencing them and their frequency and severity, Plaintiff's physician would not have prescribed the drug to Plaintiff; Plaintiff would have refused the drug; and/or Plaintiff's physician would have been able to more adequately, accurately and properly weigh and convey the risks and benefits of the drug in a way as to avoid Plaintiff's injuries and damages.

42. As a direct and proximate result of taking Cymbalta, Plaintiff suffered compensable injuries, including but not limited to the following:

a. physical, emotional, and psychological injuries;

b. past and future pain and suffering;

c. past and future mental anguish;

d. loss of enjoyment of life; and

e. past and future medical and related expenses.

FIRST CAUSE OF ACTION
PRODUCT DEFECT IN DESIGN OR FORMULATION
OHIO REVISED CODE § 2307.75

43. Plaintiff incorporates by reference, each and every paragraph of this First Amended Complaint as fully set forth herein and further alleges as follows:

44. At all relevant times hereto, Defendant manufactured, designed, formulated, produced, crated, made constructed and/or assembled Cymbalta, used by Plaintiff.

45. Defendant's Cymbalta was defective in that at the time Cymbalta left the control of Defendant's, the foreseeable risks associated with its design or formulation exceeded the benefits associated with that design or formulation.

46. The Defendants' Cymbalta was in an unsafe, defective and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiff.

47. At all times herein mentioned, Defendants' Cymbalta was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that said Cymbalta was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendants.

48. The nature and magnitude of the risk of harm associated with the design and formulation of Defendants' Cymbalta, including its propensity to induce severe withdrawal symptoms and side effects, is high in light of the intended and reasonably foreseeable use of Cymbalta for Major Depressive Disorder; Generalized Anxiety Disorder and Fibromyalgia.

49. It is highly unlikely that Cymbalta users would be aware of the risks associated with Defendants' Cymbalta through either warnings, general knowledge or otherwise. Additionally, Plaintiff was not aware of said risks.

50. The design or formulation of Cymbalta did not conform to any applicable public or private product standard that was in effect when Cymbalta left the control of its manufacturer, the Defendants.

51. The design or formulation of Defendant's Cymbalta was more dangerous than a reasonably prudent consumer would expect when used in the intended or reasonably foreseeable manner for Major Depressive Disorder, Generalized Anxiety Disorder, and/or Fibromyalgia. Thus, it was more dangerous than Plaintiff expected.

52. The intended or actual utility of Defendant Cymbalta is not of such benefit as to justify the risk of its propensity to induce severe withdrawal symptoms and side effects and other injury.

53. There were both technical and economic feasibility, at the time the Defendant Cymbalta left Defendant control, of using an alternative design or formulation that would not cause its propensity to induce withdrawal symptoms and side effects.

54. The defective design or formulation of Defendant Cymbalta was not caused by inherent characteristics of Cymbalta which is a generic aspect of all Serotonin-Norepinephrine Reuptake Inhibitor medications that cannot be eliminated without substantially compromising Cymbalta's usefulness or desirability and which are recognized by the ordinary person. This is demonstrated by numerous safer alternative therapies that are available on the market to treat male pattern baldness without the harmful side effects that can result from long-term Cymbalta use.

55. A practical and technically feasible alternative design or formulation was available that would have prevented the harm for which Plaintiff suffered.

56. By reason of the foregoing, the Defendant is liable to the Plaintiff for the manufacturing, design, formulating, producing, creating, making, constructing, and/or assembling a product that is defective in design and formulation.

SECOND CAUSE OF ACTION
PRODUCT DESIGN DEFECT DUE TO
INADEQUATE WARNING AND/OR INSTRUCTIONS
OHIO REVISED CODE § 2307.76

57. Plaintiff incorporates by reference, each and every paragraph of this First Amended Complaint as fi fully set forth herein and further alleges as follows:

58. Defendant had a duty to warn Plaintiff of the risks associated with the Defendant's Cymbalta, namely the risk of its propensity to induce severe withdrawal symptoms and side effects.

59. Defendant failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of severe withdrawal symptoms, in light of the likelihood that their product would cause severe withdrawal symptoms in patients/consumers like the Plaintiff who suffered such injury.

60. Defendant Cymbalta is defective due to inadequate post-marketing warning or instruction.

61. Defendant knew, or in the exercise of reasonable care, should have known about the risk that their product, Cymbalta, caused and has continued to cause withdrawal symptoms and side effects.

62. Defendant failed to provide post-marketing warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risks of withdrawal symptoms and side effects, in light of the likelihood that the product causes severe withdrawal symptoms, of which Plaintiff suffered.

63. Defendant's product does not contain a warning or instruction regarding including its propensity to induce withdrawal symptoms and side effects for normal healthy individuals.

64. The risk of severe withdrawal symptoms is not an open an obvious risk or a risk that is a matter of common knowledge in regards to Cymbalta.

65. By reason of the foregoing, the Defendant are liable to the Plaintiff, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective due to inadequate warning or instruction.

THIRD CAUSE OF ACTION
PRODUCT DEFECT IN FAILURE TO CONFORM TO REPRESENTATIONS
OHIO REVISED CODE § 2307.77

66. Plaintiff incorporates by reference each and every paragraph of this First Amended Complaint as if fully set forth herein and further alleges as follows: ,

67. The Defendant's product was defective in that, when it left the control of Defendant, the product did not confirm to representations made by Defendant.

68. Defendant failed to provide the appropriate warnings regarding all possible adverse side effects and complications associated with the use and discontinuation of Cymbalta.

69. When the subject Cymbalta left Defendant's control, it materially failed to conform to Defendants specifications for and representations regarding the Cymbalta product in that the severe withdrawal symptoms and side effects associated with the use of Cymbalta were non-existent and/or insignificant. The information given to consumers and physicians did not accurately reflect the risk, incidence, symptoms, scope or severity of such side effects to the consumer as compared to other similar products available in the market, which possessed lower risk of such side effects. The promotional activities of Defendant further diluted and/or minimized any warnings that were provided with the product.

70. Defendant's representations are false, misleading, and inaccurate and in stark contrast to the permanent and or persistent withdrawal symptoms or cognitive dysfunction that Defendants' Cymbalta causes.

71. As a direct and proximate result of the defective nonconformance with Defendant's representations, Plaintiff suffered severe injuries, has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering, has required and will continue to require healthcare services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

72. By reason of the foregoing, Defendant are liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, contracting, and/or assembling of a product that is defective in that it did not conform at the time it left the control of the Defendants to representations made by Defendants.

FOURTH CAUSE OF ACTION
PRODUCT DEFECT IN FAILURE TO CONFORM
WITH REPRESENTATIONS
OHIO REVISED CODE § 2307.77

73. Plaintiff incorporates by reference each and every paragraph of this First Amended Complaint as if fully set forth herein and further alleges as follows:

74. The Defendant's product was defective in that, when it left control of Defendant, the product did not conform to representations made by Defendant.

75. Defendant represented that any withdrawal/discontinuation symptoms associated with their product Cymbalta were both infrequent and if experienced in rare circumstances, was insignificant in duration and severity.

76. When the subject Cymbalta left Defendant's control, it materially failed to conform to Defendant Eli Lilly's specifications and representations regarding Cymbalta in that potential withdrawal symptoms were both infrequent and if experienced in rare circumstances, was insignificant in duration and severity.

77. Said representations are false, misleading, and inaccurate and in stark contrast to frequency, severity, and duration of withdrawal symptoms experienced by Cymbalta users, and in this case, Plaintiff.

78. As a direct and proximate result of the defective nonconformance with Defendant's representations, Plaintiff suffered severe bodily injuries, suffered mental and physical pain and suffering, will require medical care and treatment in the future, has suffered permanent injuries, has incurred lost wages or other benefits of employments, as well as a reduced capacity to earn a living and reduced vocational capacity, which are permanent.

PUNITIVE DAMAGES
OHIO REVISED CODE § 2307.80

79. Plaintiff incorporates by reference, each and every paragraph of this First Amended Complaint as if fully set forth herein and further alleges as follows:

80. Plaintiff's injury was caused by the misconduct of Defendant that manifested a

flagrant disregard of the safety of persons who might be harmed by the product in question.

81. Defendant fraudulently, and in violation of applicable regulations of the FDA, withheld from the FDA information known to Defendants to be material and relevant to the harm that the Plaintiff suffered, or misrepresented to the FDA information of that type.

82. By reason of the foregoing, Defendant is liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling of a product that is defective in that it did not conform at the time it left the control of the Defendant to representations made by Defendant.

FIFTH CAUSE OF ACTION VIOLATION OF UNFAIR AND DECEPTIVE TRADE PRACTICES ACT

83. Plaintiff incorporates by reference each and every paragraph of this First Amended Complaint as if fully set forth herein and further alleges as follows:,

84. Defendant has a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion and sale of Cymbalta.

85. Had the Defendant not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Cymbalta, and would not have incurred related medical costs. Specifically, Plaintiff, his physician, and medical staff were misled by the deceptive conduct described herein.

86. Defendant's deceptive, unconscionable, and/or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statue listed below.

87. Defendant engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of the Ohio Consumer Sales Practice Act § 1345 *et seq*. and Ohio Deceptive Trade Practices Act § 4165 *et seq*.

88. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendant's conduct directed at patients, physicians, and consumers was to create a demand for and sell Cymbalta. Each aspect of Defendant's conduct combined to artificially

create sales of Cymbalta.

89. The medical community relied upon Defendant misrepresentations in deciding to use Cymbalta.

90. By reasons of the unlawful acts engaged in by Defendant, Plaintiff suffered and continues to suffer ascertainable loss and damages.

91. As a direct and proximate result of Defendants' violations of the unfair trade practices act, Plaintiff has sustained economic losses and other damages for which he is entitled to statutory and compensatory damages, and declaratory relief, in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

92. Plaintiff incorporates by reference each and every paragraph of this First Amended Complaint as if fully set forth herein and further alleges as follows:,

93. Defendant carelessly and negligently manufactured, marketed and sold Cymbalta to Plaintiff, carelessly and negligently concealed these defects from Plaintiff, and carelessly and negligently misrepresented the quality and safety of Cymbalta. Defendant should have realized that such conduct involved an unreasonable risk of causing emotional distress to a reasonable person that might, in turn, result in illness or bodily harm.

94. Defendant owed a duty to treating physicians and Plaintiff to accurately and truthfully represent the risks of Cymbalta. Defendant breached that duty by misrepresenting and/or failing to adequately warn of the risk of Cymbalta, including but not limited to the severity of the withdrawal risks associated with Cymbalta – effects of which Defendant knew or in the exercise of diligence should have known – to the treating physicians and Plaintiff.

95. As a direct and proximate result of Defendant's wrongful conduct and breach of duty, Plaintiff has sustained and will continue to sustain severe emotional distress either due to physical injury or a rational fear of physical injury and is entitled to recovery of damages in an amount to be proved at trial. Defendant is liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiff is entitled by law in an amount to be proven at trial.

PRAYER FOR RELIEF

96. WHEREFORE, Plaintiffs respectfully pray for judgment against Lilly as follows:

a. Judgment in favor of Plaintiffs and against Lilly, for all damages in such amounts as may be proven at trial;

b. Compensation for economic and non-economic losses, including but not limited to, past and future medical expenses, medical monitoring, out-of-pocket expenses, past and future physical pain and mental anguish, past and future physical impairment, past and future loss of companionship and consortium, and past and future loss of household services, in such amounts as my be proven at trial;

c. Past and future general damages, according to proof;

d. Any future damages resulting from permanent injuries;

e. Psychological trauma, including but not limited to mental anguish, mental distress, apprehension, anxiety, emotional injury, psychological injury, depression, and aggravation of any pre-existing and/or underlying emotional or mental diseases or conditions;

f. Pain and suffering;

g. Loss of enjoyment of life;

h. Punitive and exemplary damages in an amount to be determined by trial;

i. Attorneys' fees and costs;

j. Treble damages;

k. Prejudgment and post-judgment interest;

l. Costs to bring this action; and

m. Any such other and further relief as the Court may deem just and proper in law or in equity.

DEMAND FOR JURY TRIAL

Plaintiffs respectfully request a jury trial of all issues presented in this Complaint.

DATED: February 9, 2015

LEESEBERG & VALENTINE

By: /s/ Craig S. Tuttle
Craig S. Tuttle, Esquire
175 South Third Street
Columbus, OH 43215
ctuttle@leesebergvalentine.com
(p) (614) 221-2223
(f) (614) 221-3106

Of Counsel:

Harris L. Pogust, Esq.
T. Matthew Leckman, Esq.
POGUST BRASLOW & MILLROOD, LLC
Eight Tower Bridge, Suite 1520
161 Washington Street
Conshohocken, PA 19428
hpogust@pbmattorneys.com
mleckman@pbmattorneys.com

Michael L. Baum, Esq.
Brent Wisner, Esq.
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025